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CLINICAL RESEARCH

Collagen plug-based vascular closure devices do not decrease vascular and bleeding complications occurring after balloon aortic valvuloplasty



Les dispositifs de fermeture vasculaire percutanée à base de collagène ne diminuent pas les complications vasculaires et hémorragiques après valvuloplastie percutanée

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KEYWORDS

Vascular closure devices;
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Summary

Background. — The benefits of vascular closure devices (VCDs) in the prevention of vascular complications after femoral intervention remain controversial.

Aim. — To evaluate the efficiency of collagen plug-based VCDs in the prevention of femoral access complications after balloon aortic valvuloplasty.

Methods. — We conducted a prospective analysis of consecutive patients who underwent balloon aortic valvuloplasty by femoral retrograde technique in our centre between 2009 and 2012. Group 1 included 75 patients in whom femoral puncture haemostasis was obtained with the use of an 8F collagen plug-based VCD (Angio-Seal™; Saint-Jude Medical, Inc.); group 2 included

Abbreviations: BAV, balloon aortic valvuloplasty; CI, confidence interval; OR, odds ratio; PCI, percutaneous coronary intervention; RR, relative risk; TAVI, transcatheter aortic valve implantation; VCD, vascular closure device.

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105 patients who had manual or mechanical groin compression (FemoStop™; RADI Medical Systems, Inc.). We did not use heparin during the procedure. We collected data on major in-hospital adverse events, major bleeding (Bleeding Academic Research Consortium classification ≥ 3) and vascular access complications.

Results. — We included 180 patients with severe and symptomatic aortic stenosis. Indications for valvuloplasty were mainly bridge to transcatheter aortic valve implantation or palliative therapy (72%). The groups were similar in terms of median age, lower limb artery disease and body mass index. Vascular and bleeding complications occurred in 11.1% of patients and were not decreased with the use of VCDs (relative risk 2.60, 95% confidence interval 1.10–3.09; $P=0.05$). These findings were consistent across all prespecified subgroups. Duration of hospital stay was not reduced by VCDs.

Conclusions. — Based on the results of this study, performed with small-size sheaths and without heparin, collagen plug-based VCDs increase femoral access complications following aortic valvuloplasty. Systematic use of VCDs in elderly patients, with probable advanced limb atherosclerosis, is questionable.

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MOTS CLÉS

Fermeture vasculaire
percutanée ;
Complications
vasculaires ;
Valvuloplastie
aortique au ballon

Résumé

Contexte. — L'intérêt des dispositifs de fermeture vasculaire pour prévenir les complications vasculaires après intervention percutanée fémorale reste controversé. Ceux-ci ont par ailleurs été évalués essentiellement après angioplastie coronaire.

Objectif. — Évaluer l'efficacité des dispositifs de fermeture percutanée à base de collagène pour prévenir les complications vasculaires après valvuloplastie aortique au ballon.

Méthodes. — Il s'agit d'une étude prospective menée entre 2009 et 2012, incluant 180 patients consécutifs qui bénéficient d'une valvuloplastie aortique au ballon par voie fémorale rétrograde pour sténose aortique serrée. Dans le groupe 1 ($n=75$), un dispositif de fermeture percutané de taille 8F (Angio-Seal™ ; Saint-Jude Medical, Inc.) est utilisé au niveau de l'abord vasculaire fémoral ; dans le groupe 2 ($n=105$), une compression fémorale manuelle ou mécanique est réalisée (FemoStop™, RADI Medical Systems, Inc.). L'héparine n'est pas utilisée pendant la procédure. Les complications intra-hospitalières majeures, les complications vasculaires et les événements hémorragiques graves (\geq BARC classe 3) sont évaluées.

Résultats. — La valvuloplastie aortique est faite essentiellement en « pont » avant TAVI ou en traitement palliatif ($n=130$; 72 %). Les deux groupes ont des caractéristiques cliniques similaires : âge moyen 84 ans, antécédent d'artériopathie périphérique et index de masse corporelle. Des complications vasculaires ou hémorragiques sont observées parmi 11,1 % des patients et sont significativement plus fréquentes dans le groupe 1 (RR 2,60, 95 % CI 1,10–3,09 ; $p=0,05$). Ces résultats sont observés dans tous les sous-groupes prédéfinis. La durée de l'hospitalisation n'est pas différente entre les 2 groupes ($p=0,3$).

Conclusions. — Cette étude montre des résultats défavorables en termes de complications vasculaires et hémorragiques des dispositifs de fermeture percutanée utilisés après valvuloplastie aortique réalisée avec de petits désilets et sans héparine. L'utilisation systématique de ces dispositifs chez des patients âgés avec athérosclérose fémorale fréquente apparaît discutable.

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Introduction

A resurgence of balloon aortic valvuloplasty (BAV) has taken place during the past decade, alongside a rapid expansion in the population of elderly patients with severe aortic stenosis and significant co-morbidities and the development of percutaneous valve replacement therapies [1–5].

Whereas the complications of BAV have been markedly reduced by improvements in techniques and materials, the main risks of the procedure remain (i.e. complications at the

femoral entry site, with a high risk of bleeding, the need for blood transfusion or vascular lesions, which can affect up to 10% of patients) [2,5–8]. Reducing vascular and bleeding events has become an important goal in interventional cardiology, because they are associated with mortality, morbidity and prolonged hospitalization [9,10].

Vascular closure devices (VCDs), which are frequently used to obtain rapid femoral haemostasis and patient deambulation, are controversial with regard to their ability to prevent femoral vascular access complications. The use

of these devices in the particular setting of BAV has only been evaluated in small and retrospective series [11,12]. This question is of major concern, because BAV needs large French size arterial puncture and is usually performed in elderly patients, who often have advanced lower limb atherosclerosis, which may increase the risk of vascular complications.

The objective of this prospective study was to compare VCDs with manual or mechanical compression in terms of the occurrence of femoral vascular access and bleeding events.

Methods

Patient population

All patients who were referred to the Department of Cardiology at the University Hospital of Montpellier, France for BAV between 2008 and 2012 were included in this prospective study. All the patients had severe symptomatic aortic stenosis secondary to degenerative disease, confirmed by transthoracic echocardiography (mean gradient > 40 mmHg and/or $S < 1$ cm²), and were not candidates for aortic valve replacement. The logistic euroSCORE (European System for Cardiac Operative Risk Evaluation) was calculated for all patients [13]. Patients with significant (> 2) aortic regurgitation and lack of femoral vascular access were excluded. For all patients, there was discussion of the therapeutic options for treating aortic stenosis, including an assessment of the risks of BAV and of surgical aortic valve replacement. Patients were referred for BAV for palliation of heart failure symptoms, treatment of cardiogenic shock or as a bridge to transcatheter aortic valve implantation (TAVI), surgical aortic valve replacement or non-cardiac surgery. Anticoagulation therapy with vitamin K antagonists was withdrawn before BAV, and the procedure was performed when the international normalized ratio was < 2 . Platelet anti-aggregation therapy was continued.

Balloon aortic valvuloplasty procedure

The BAV procedure was performed by the same operating team of three experienced interventional cardiologists according to the standard technique via the retrograde femoral approach, using 8F or 9F sheaths. The aortic valve was crossed under fluoroscopic guidance with a 0.034-inch straight guidewire through an Amplatz catheter (Boston Scientific, Marlborough, MA, USA). The aortic valve gradient was measured from simultaneous pressure recordings from the left ventricle and the descending aorta through the sheath. An Amplatz 0.038-inch Stiff™ guidewire (Boston Scientific) is shaped to have a curved tip; it was advanced into the left ventricle through the Amplatz catheter and left in place while the Amplatz catheter was removed under fluoroscopic guidance. BAV was performed by using 20F, 22F or 23F non-compliant dilatation balloons catheters (Tyshak™; B. Braun Interventional Systems, Inc., Bethlehem, PA, USA). To stabilize the balloon position across the valve, the heart was paced at a high rate (180–200 beats/min) through the use of a temporary pacemaker positioned in the right ventricle through the femoral vein. The goal was to obtain a mean pressure gradient < 20 mmHg or a decrease in the

initial gradient of 50%. If this goal was not achieved and no procedural complications occurred, the procedure could be repeated using a larger balloon catheter, but without exceeding a balloon/ring ratio of > 1.2 .

Patients were divided into two groups according to femoral puncture site haemostasis method. Group 1 consisted of patients who had femoral closure with a collagen plug-based VCD (8F Angio-Seal™; St. Jude Medical, Inc., St. Paul, MN, USA); group 2 included those who had manual compression of the femoral puncture site, aided or not by a compression device (FemoStop™; RADI Medical Systems, Inc., Uppsala, Sweden). The three interventional cardiologists had experience with the device, as they had used it for several years for femoral intervention, with sheath sizes between 6F and 9F. The choice of whether or not to use a VCD during the procedure was left at the discretion of the interventional cardiologist. In accordance with recent reports, we did not use heparin during the procedure [14]. We recommended that all patients remained in an elongated position until the day after the procedure; however, patients with devices without vascular complications could sit in the bed after 2 hours. A pressure bandage was applied in all patients in the manual compression group, but not in the VCD group without bleeding or vascular complications.

Clinical endpoints

Clinical events were evaluated during the hospital stay and at 1-month follow-up, and were compared between the two groups of patients. Our primary combined endpoint was evaluation of severe vascular and bleeding complications. Severe vascular complications included femoral pseudoaneurysm or arteriovenous fistulae requiring surgery or endovascular intervention, acute limb ischaemia and groin infection. Severe bleeding events were defined as a score ≥ 3 according to the Bleeding Academic Research Consortium classification [15].

Our secondary endpoint was all adverse events, including death, heart failure, significant aortic regurgitation, myocardial infarction (defined as a rise in troponin greater than 3 times the 99th percentile of the upper reference limit), stroke, mesenteric ischaemia or systemic embolism. We also evaluated duration of hospital stay in the two groups.

Statistical analysis

Patient characteristics are presented using medians and 25–75% interquartile ranges or means \pm standard deviations for continuous variables and frequencies and proportions for categorical variables. The two groups were compared using the Kruskal–Wallis test for continuous variables and the Chi² or Fisher's test for categorical variables. Relative risks (RRs) and their 95% confidence intervals (CIs) were calculated between the two groups. A multivariable analysis of the factors associated with severe complications was carried out using logistic regression, using a backward selection of the variables. The α -to-enter and α -to-exit were set at 0.20 and 0.15, respectively. Odds ratios (ORs) with 95% CIs were calculated. The statistical bilateral significance threshold was set at 5%. Statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC, USA).

Results

Patient population

Between 2008 and 2012, 180 consecutive patients underwent BAV (six repeat procedures, four second repeat procedures), including 75 patients (41.7%) with femoral closure obtained with a VCD (group 1) and 105 patients (58.3%) who had manual or mechanical compression of the femoral puncture site (group 2).

The baseline characteristics of the patients (Table 1) were identical between the two groups: same median age (84 years), prevalence of peripheral vascular disease (overall $n=47$; 26%), body mass index (mean 27 kg/m^2) and existence of previous platelet anti-aggregation therapy (overall $n=100$; 55%). The main indications for BAV were palliative procedure or bridge to TAVI ($n=130$; 72%); other indications were bridge to surgery ($n=35$; 19%) and cardiogenic shock ($n=15$; 8%). A good haemodynamic result with a decrease in initial gradient of at least 50% was obtained in all patients.

Severe vascular and bleeding complications

The primary composite endpoint was achieved in 20 patients (11.1%) overall. Major bleeding was the most common adverse event, occurring in 16 patients (8.9%), whereas severe vascular complications occurred in seven patients (3.9%) (Table 2). Acute limb ischaemia occurred in six patients (3.3%) – five of whom belonged to the VCD group ($P=0.08$) – and was related to device obstruction, according to peroperative data. We observed groin infection in three patients, all of whom were in group 1 (4%; $P=0.07$) and had vascular complications (pseudoaneurysm).

The use of a VCD was therefore associated with an increased risk of vascular and bleeding complications in general (RR 2.60, 95% CI 1.10–3.09; $P=0.05$); the risk particularly concerned major bleeding complications, which were significantly increased with VCD use (4.7% vs 14.6%; $P=0.02$).

Unsuccessful deployment of the device occurred in five patients in the VCD group (6.6%), three of whom had vascular complications (two pseudoaneurysms and one large haematoma requiring transfusion).

The majority of vascular complications occurred during the first day after deployment of the device (80%).

Secondary endpoints

Overall, seven (3.9%) patients died during follow-up: three patients (4.0%) in group 1 and four patients (3.8%) in group 2 ($P=0.60$). Death was related to cardiogenic shock caused by severe left ventricular dysfunction in three cases, and to annular rupture during the procedure in one patient. One death was related to severe pulmonary infection, which occurred in a patient who had acute limb ischaemia (group 1). One death was related to renal failure in a patient with a large groin haematoma after failure of device deployment (group 1).

One patient in group 2 had an atrioventricular block requiring pacemaker implantation. In four patients (two in each group), we observed mild aortic regurgitation after the

procedure. Duration of hospital stay was 5 ± 4 days, with no significant difference between the two groups (6 ± 2 vs 5 ± 3 days; $P=0.3$).

Predictive factors for vascular and bleeding complications

Age ($P=0.14$), left ventricular ejection fraction ($P=0.04$), New York Heart Association class ($P=0.20$), history of peripheral vascular disease ($P=0.20$), body mass index $< 25 \text{ kg/m}^2$ ($P=0.05$) and platelet anti-aggregation therapy ($P=0.5$) were not associated with the primary outcome. Among patients with lower body mass index ($< 25 \text{ kg/m}^2$), the primary endpoint was achieved in 20% in group 1 ($n=3$) and in 22% in group 2 ($n=4$) ($P=0.5$). After adjustment for the above factors, the use of a VCD remained associated with the occurrence of severe complications (adjusted OR 1.64, 95% CI 95% 1.20–4.2; $P=0.02$).

Discussion

In this single-centre prospective study including 180 consecutive patients, the use of a VCD after balloon aortic valvuloplasty generates a higher risk of vascular and bleeding complications (RR 2.60; $P=0.05$) compared with manual or mechanical compression of the femoral puncture site. The risk of major bleeding was significantly increased with the use of a VCD ($P=0.02$). The trend towards increased acute limb ischaemia ($P=0.08$) related to device obstruction should also be noted. Duration of hospital stay was not reduced by the use of a VCD.

Use of vascular closure devices after percutaneous femoral interventions

VCDs are medical devices that were introduced in the early 1990s in an effort to reduce the time to haemostasis, to obtain early ambulation and improve patient comfort after femoral angiography or percutaneous coronary intervention (PCI). Most VCDs focus on technologies involving a suture (Perclose™; Abbott Vascular, Redwood City, CA, USA) or a collagen plug (Angio-Seal). The Angio-Seal device is among the most widely used of the VCDs [16].

Currently, there is no compelling evidence that VCDs lower complication rates or have an impact on major access site bleeding. Clinical data mainly come from non-randomized post-hoc subgroup analyses based on small underpowered studies or meta-analyses. In all these studies, the decision to use a VCD was always left at the discretion of the operator.

In the ACUITY trial of 11,983 patients who underwent femoral angiography or PCI, 4307 (35.9%) received a VCD (Angio-Seal in 2971 patients). In the PCI group, the use of a VCD reduced access site bleeding by 22% according to a post-hoc analysis. However, this trial only focused on major access site bleeding and did not consider other vascular complications, such as pseudoaneurysm, arteriovenous fistula or limb ischaemia. Furthermore, patients who did not receive a VCD had a higher rate of hypertension and renal insufficiency, and more frequently had elevated biomarkers and anaemia, which may have increased the likelihood of

Table 1 Baseline characteristics of patients who underwent balloon aortic valvuloplasty at Montpellier University Hospital, between 2008 and 2012.

	Group 1 (VCD) (n = 75)	Group 2 (no VCD) (n = 105)	P
Age (years)	84 (78–87)	84 (80–89)	0.37
Men	38 (50.6)	46 (43.8)	0.58
Diabetes	21 (28.0)	24 (22.8)	0.55
BMI (kg/m ²)	27 ± 4	25 ± 4	0.60
LVEF			0.92
> 45%	42 (56.0)	58 (55.2)	
35–35%	15 (20.0)	17 (16.1)	
25–35%	10 (13.3)	15 (14.2)	
< 25%	8 (10.6)	15 (14.2)	
NYHA functional class			0.12
I or II	14 (18.6)	21 (20.0)	
III	27 (36.0)	40 (38.1)	
IV	34 (45.3)	45 (42.8)	
Peripheral vascular disease	21 (28.0)	26 (24.7)	0.79
Coronary artery disease	45 (60.0)	50 (47.6)	0.17
Platelet anti-aggregation therapy	48 (64.0)	52 (49.5)	0.55
Creatinine clearance < 30 mL/min ^a	10 (13.3)	12 (11.4)	0.60

Data are median (interquartile range), mean ± standard deviation or number (%); BMI: body mass index; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; VCD: vascular closure device.

^a By the Modification of Diet in Renal Disease equation.

intervention because of haemorrhage in this group [10]. In a cost-effectiveness analysis, Bos et al. [17] showed that the use of Angio-Seal did not reduce pseudoaneurysm and arteriovenous fistulas. From the New England Women PCI registry, Ahmed et al. [18] reported a 28% reduction in risk of bleeding with VCDs, significant only in patients at high risk of bleeding. The results of meta-analyses are discordant. The meta-analysis of Nikolsky et al. [19] involved a total of 30 studies concerning 37,066 patients. The risk of access site-related complications was similar for Angio-Seal compared with mechanical compression. The meta-analysis of Vaitkus et al. [20] included 16 studies enrolling 5048 patients after diagnostic catheterization and PCI. The Angio-Seal device

was associated with a significant reduction in risk (OR 0.51) and Perclose had a neutral result (OR 1.0), whereas the VasoSeal™ device (Datascope Corp., Montvale, NJ, USA) had an increased risk of complications (OR 1.18). More recently, Gurm et al. [21], in an observational cohort study concerning 28,528 angioplasty procedures using VCDs, showed that the devices were associated with reductions in vascular complications (OR 0.78, [95% CI 0.67–0.90]; *P* = 0.001) and transfusions.

VCDs have introduced a new set of iatrogenic complications, some of which are virtually exclusive to VCDs, such as infection, which is an uncommon but extremely serious complication, and femoral obstruction by

Table 2 Vascular and bleeding complications according to vascular closure device use.

	Group 1 (VCD)(n = 75)	Group 2 (no VCD) (n = 105)	P
Vascular complications and/or bleeding, in general (n = 20; 11.1%)	12 (16.0)	8 (7.6)	0.05
Pseudoaneurysm and AV fistula (n = 7; 3.9%)	5 (6.6)	2 (1.9)	0.13
Groin infection (n = 3; 1.7%)	3 (4.0)	0	0.07
Acute limb ischaemia (n = 6; 3.3%)	5 (6.6)	1 (0.9)	0.08
Dissection (n = 4; 2.2%)	2 (2.7)	2 (1.9)	0.86
Major bleeding (≥ BARC classification 3) (n = 16; 8.9%)	11 (14.6)	5 (4.7)	0.02
RBC transfusion > 1 (n = 11; 6.1%)	9 (12.0)	2 (1.9)	0.008
Retroperitoneal haematoma (n = 1; 0.6%)	1 (1.3)	0	0.42

Data are number (%); AV: arteriovenous; BARC: Bleeding Academic Research Consortium; RBC: red blood cell; VCD: vascular closure device.

the device, leading to acute limb ischaemia or retroperitoneal haemorrhage [21–23]. In our study, we observed five patients who had acute limb ischaemia related to device obstruction in the VCD group. One of these patients died as a result of acute renal failure after prolonged hospitalization.

VCD failure is rare, but when the device does fail, it is associated with a significant increase in the risk of vascular complications. From a prospective registry of 9823 consecutive patients undergoing cardiac catheterization, Bangalore et al. [24] showed that unsuccessful deployment or failure to achieve haemostasis was observed in 3.0% of PCI patients and was associated with a significantly increased risk of any major or minor vascular complications (6.7% vs 1.4%; $P < 0.0001$). The authors observed an increased risk of VCD failure with a suture-based device compared with a collagen plug-based device ($P < 0.001$) [24].

In our study, in which only collagen plug-based devices were considered, six patients (6.6%) had unsuccessful deployment of the device; three of these patients had vascular complications, indicating the severity of this event. The rate of failure was higher than that observed by Ben Dor et al., probably because our study involved more elderly patients with atherosclerotic arteries. Furthermore, the use of larger sheaths (8F and 9F) than those used for diagnostic and therapeutic coronary interventions (4F to 6F) may have contributed to our results [24].

Use of vascular closure devices after balloon aortic valvuloplasty

While BAV requires larger sheaths than those usually used after percutaneous coronary intervention, and heparin is frequently associated with the procedure, VCDs may be useful for reducing the duration of femoral compression and allowing rapid patient deambulation.

However, in the specific BAV setting, the results of VCDs have been poorly evaluated. Marchant et al. reported their clinical experience of successful access site management with the pre-close technique after aortic valvuloplasty in four patients [11]. Solomon et al. [12] reviewed 31 consecutive patients who underwent percutaneous aortic valvuloplasty and suture closure with the Perclose device between April 1998 and September 2000. Compared with 39 consecutive prior patients who had their arterial puncture managed with manual compression, stay duration was shorter (2.2 vs 5.3 days) and fewer patients received blood transfusions (0% vs 29%). This study was only retrospective and vascular complications were not evaluated precisely [12]. Ben Dor et al. [25] reported results of a cohort study of 333 patients who had suture-based and collagen-based VCDs or manual compression after BAV, using 10F to 13F sheaths; they observed that serious vascular complications or blood transfusions were higher in the manual compression group ($P < 0.001$). Our results were contradictory, but can probably be explained by the lower size of the sheaths (8F or 9F) in our study and the absence of the use of heparin during the procedure. Therefore, the rate of bleeding or vascular complications with manual compression in our study was less than half of that observed in the cohort of Ben Dor et al. (7.6% vs 17%) [25].

Because VCDs remain to be clinically proven and have added costs, assessment of their potential advantages and adverse events in a population of elderly patients, who often have significant lower extremity atherosclerosis, is of major concern. Our prospective study involved 180 elderly patients, including 47 patients (26%) with lower limb arteriopathy, and showed an increase in vascular and bleeding complications in general (RR 2.60; $P = 0.05$), associated with a significant increase in major bleeding complications ($P = 0.02$) when using these devices. These results were observed without the use of heparin during the procedure and with the use of small-size sheaths (8F or 9F). Additionally, our results showed a trend towards increased acute limb ischaemia with VCDs, which can be a serious complication that requires urgent surgical management; two of the deaths concerned these types of patients. Groin infection was seen in three patients, all in group 1; this is a severe event that leads to prolonged hospital stay and is frequently associated with vascular complications [23]. Patients with lower body mass index (25 kg/m^2 ; $n = 33$) tended to have more femoral access complications ($P = 0.05$), but did not take advantage of VCDs in our study ($P = 0.5$). These results are in accordance with those of Gurm et al., who reported that the benefit of VCDs over manual closure after coronary angioplasty was attenuated in this subgroup [21]. Lastly, the devices used in our study did not reduce the duration of hospital stay, which accounts for a significant part of the hospital cost, probably because the increased rate of vascular complications affects the duration of hospitalization.

These results are somewhat different from those observed with coronary diagnostic or therapeutic interventions, where VCDs have neutral or beneficial effects on bleeding complications, and may often reduce the duration of hospital stay. In our population of elderly patients, who probably had calcified and atherosclerotic arteries, a large (8F) VCD did not seem to be beneficial and could even be harmful in some cases. While the majority of vascular complications occurred during the first day after deployment, we can assume that the femoral arterial wall was weakened by the device and broke a few hours after its introduction.

Despite the potential benefit of VCDs in terms of early ambulation and comfort [17,18,22,26], our results argue against the systematic use of these collagen devices, which should be limited to patients at high risk of bleeding with manual compression (e.g. requiring anticoagulant therapy). Then, the American Heart Association guidelines recommend such therapy, stating that VCDs should not be used routinely for the specific purpose of reducing vascular complications in patients undergoing invasive cardiovascular procedures via the femoral artery approach (class III, level of evidence C) [27].

Study limitations

The non-randomized nature of our study is a limitation, as it can lead to potential bias regarding the choice of whether or not to use a VCD. Given the increased use of BAV as a bridge to TAVI in our centre since 2009, operator experience may have increased, leading to a reduction in the rate of complications with the device.

There is a learning curve for the use of VCDs [23], and it is likely that better patient selection and improved knowledge of the device result in lower rates of vascular complications. However, the three interventional cardiologists had several years of experience with the device before beginning the study.

We did not use heparin to perform valvuloplasty in our study. While devices are usually used and recommended in patients at high risk of bleeding, it may contribute to increasing the safety of manual compression.

Even if collagen haemostatic devices like Angio-Seal seem to be the most secure VCDs [22,25], these results can not be extended to other devices, such as Perclose suture devices.

Duration of hospital stay was not influenced by the device; many medical or social factors unrelated to vascular complications may influence the duration of hospital stay in elderly patients.

Conclusions

Based on the results of this prospective observational study, compared with manual compression, collagen plug-based VCDs significantly increased vascular and bleeding complications occurring after BAV performed with low size (8F and 9F) sheaths and without heparin use. Except for patients at high risk of bleeding with manual compression, the systematic use of such devices in a population of elderly patients with probable advanced limb atherosclerosis is questionable.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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